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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Seattle District
Pacific Region
22201 23rd Drive S.E.
P.O. Box 3012
Bothell, WA 98041-3012

Telephone: 206-486-8788
FAX: 206-483-4996

July 30, 1997

HAND CARRIED

In reply refer to Warning Letter SEA 97-23

Mary L. Brueggeman
Executive Director
Providence Home Services
2731 Wetmore, Ste 520
Everett, WA 98201-3581

WARNING LETTER

Dear Ms. Brueggeman:

Inspection of Providence Northwest Washington Home Health Supply Company, 700 Avenue D, Snohomish, Washington, was conducted on May 30-June 3, 1997 by Investigators Connie P. Rezendes and Paula J. Wilkerson, of the Food and Drug Administration (FDA). They observed deviations that cause the drug products manufactured at this facility to be adulterated within the meaning of Section 501(a)(2)(B) of the Federal Food, Drug, and Cosmetic Act.

The Snohomish facility's product, Oxygen, USP, is adulterated in that the controls used for the manufacture, processing, packing, or holding of this product are not in conformance with the current good manufacturing practice regulations (Title 21, Code of Federal Regulations, Parts 210 and 211).

Observations include:

1. Failure to properly calibrate the Oxygen Analyzer used for the assay of Oxygen, USP, in that your firm did not have the high purity nitrogen standard required to calibrate the "zero" on the meter [21 CFR 211.160(b)(4)].

2. Failure to maintain complete records of the periodic calibration of the oxygen analyzer, in that there is no documentation that the required weekly filter checks are being performed [21 CFR 211 194(d)].

The above identification of violations is not intended to be an all-inclusive list of deficiencies at the Snohomish location. It is your responsibility to assure adherence with each requirement of the Good Manufacturing Practice Regulations. Federal agencies are advised of the issuance of all warning letters about drugs so that they may take this information into account when considering the award of contracts. FDA recommends against the award of contracts for affected products.

You should take prompt action to correct these deviations. Failure to promptly correct these deviations may result in regulatory action without further notice. Possible actions include seizure and/or injunction.

Please notify this office in writing within fifteen (15) days of receipt of this letter of the specific steps you have taken to correct the noted violations, including an explanation of each step being taken to prevent the recurrence of similar violations. Provide sufficient documentation to allow for evaluation of your actions. If corrective action cannot be achieved with 15 working days, please state the reason for delay and the time-frame in which correction will be accomplished.

Your reply should be directed to H. Tyler Thornburg, Compliance Officer, Food & Drug Administration, PO Box 3012, Bothell, WA 98041-3012.

Sincerely yours,

Walter E. Hill for
Roger L. Lowell
District Director

Enclosures:
Compressed Medical Gases Guideline, February 1989
Form FDA-483 dated 6-6-97

cc: (letter only)
Ms. Ronnie Eaton, General Manager
Providence Northwest Washington Home Health Supply
700 Avenue D
Snohomish, WA 98290